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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,872	04/10/2001	Brian J. Stockman	6311.N	7416

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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	09/829,872		STOCKMAN, BRIAN J.	
	Examiner		Art Unit	
	Michael Borin		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) see below . 6) ☐ Other: _____

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DETAILED ACTION

Status of Claims

Response to restriction requirement filed 09/29/2003 is acknowledged. Applicant elected, with traverse, Group I, claims 1-8, 17-22. Applicant argues that claims of Group I do not exclude obtaining quantum correlation spectrum required by the claims of Group II. Examiner maintains that Group I does not explicitly requires obtaining quantum correlation spectrum and a reference teaching method of Group I would not necessarily teach steps of method of Group II. See, for example, references used in the art rejection below. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 9-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups. Cancellation of claims 9-15 is requested.

Information Disclosure Statement

Applicants' Information Disclosure Statements filed 01/11/2002, 03/15/2002, 05/03/2002, 06/09/2002, 01/22/2003 have been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

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Although a concise explanation of the relevance of information is not required for English language information, applicants are encouraged to provide a concise explanation of why the English-language information is being submitted. Concise explanations (especially those that point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more is highly relevant to patentability. M.P.E.P. § 609. This statement is in accord with *dicta* from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), which states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888. This case presented a situation where the disclosure was in excess of 700 pages and contained more than fifty references. *Id.* 1888. A cursory glance at the M.P.E.P. also provides more support for this position. In a subsection entitled "Aids to Compliance With Duty of Disclosure," item thirteen states:

It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant information and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to Applicant's attention and/or are known to be of the most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F.Supp 948 (S.D. Fla. 1972) *aff'd* 479 F.2d 1338 (5th Cir 1974); [*Molins*]."

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MPEP 2004. Therefore it is recommended that if any information that has been cited by Applicants in the previous disclosure statement, is known to be material for patentability as defined by 37 CFR 1.56, Applicant should present a concise statement as to the relevance of that/those particular documents therein cited.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 17 (and claims dependent thereupon) are confusing in that in the first method steps they recite "atoms" , and it is not clear whether atoms of ligand, protein, or both are meant.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use

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the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 17-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The instant claims are drawn to NMR method for identifying binding site of pappilomavirus E2 protein. The disclosure is limited to a particular strain, HPV-18 strain of pappilomavirus E2, and Table 1, which is critical for execution of the method is limited to information on said HPV-18 strain of pappilomavirus E2. There is no indication that applicant is in possession of method of identifying of sites in a protein derived from any other virus.

Claims 1-8, 17-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method for identifying binding site of HPV-18 strain of pappilomavirus E2 protein, does not reasonably provide enablement for identifying of sites in a pappilomavirus E2 protein derived from any other virus. The method claims are strictly limited to use of Table 1, which is a table of chemical shifts of DNA-binding domain (DBD) of HPV-18 strain of pappilomavirus E2 protein

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(see specification, p. 6, lines 5-6, and p. 9 +). There are no working examples or guidance on how to use spectral information obtained from one protein for characterizing spectral information obtained from other species. Accordingly, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103[©] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable

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over Veeraraghavan et al., 1999¹ or Veeraraghavan et al.², 1998 or Hajduk et al.³

The instant claims are drawn to NMR method of identifying binding of ligand (such as DNA) to binding site of papillomavirus E2 protein, wherein the method comprises providing set of chemical shifts for atoms of DNA binding site of papillomavirus E2 protein in the presence of a ligand, comparing the set with the second set obtained in the absence of the ligand (Table 1) and thus identifying interacting atoms as those atoms that exhibit changes in chemical shift. Further, claims 17-22 specify that method is computer-assisted.

All three references identify ¹H, ¹⁵N, or ¹³C NMR chemical shifts of atoms comprising binding site of papillomavirus E2 protein and teach NMR method of identifying binding of DNA to binding site of papillomavirus E2 protein comprising providing set of chemical shifts for atoms of DNA binding site of papillomavirus E2 protein in the presence and absence of the ligand (DNA in Veeraraghavan et al or

¹Veeraraghavan et al., 1999 (Structural Correlates for Enhanced Stability in the E2 DNA- Binding Domain from Bovine Papillomavirus. *Biochemistry*, 1999, 38(49), 16115-16124; reference submitted by applicant)

² Veeraraghavan et al *Journal of Biomolecular NMR* (1998), 11(4), 457-458;

³Hajduk et al. NMR-Based Discovery of Lead Inhibitors That Block DNA Binding of the Human Papillomavirus E2 Protein. *Journal of Medicinal Chemistry* (1997), 40(20), 3144-3150

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inhibitors of DNA binding in Hajduk et al), comparing the sets and thus identifying interacting atoms as those atoms that exhibit changes in chemical shift.

The difference of the instantly claimed method is the use of Table 1, which is a table of chemical shifts of DNA-binding domain (DBD) of papillomavirus E2 in the absence of ligands (see specification, p. 6, lines 5-6, and p. 9+).

However, as MPEP 2106 notes,

"Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). Common situations involving nonfunctional descriptive material are:

- a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium,
- a computer that differs from the prior art solely with respect to nonfunctional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of nonfunctional descriptive material." (emphasis added)

In the instant case, the Table 1 is nonfunctional descriptive material which does not distinguish the invention from the prior art. Therefore, the referenced prior art teaches all of the functional elements of the claims.

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Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

December 9, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

